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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,477	04/20/2004	Swee Hin Teoh	NUS-8 DIV I	4933

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EXAMINER

WOODWARD, CHERIE MICHELLE

ART UNIT	PAPER NUMBER
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1647

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/828,477	Applicant(s) TEOH ET AL.	
	Examiner CHERIE M. WOODWARD	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40,43,44,48,56, and 59-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40,43,44,48,56 and 59-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Formal Matters

1. Applicant's Response, filed 27 July 2009, is acknowledged and entered. Claims 1-39, 41, 42, 45-47, 49-55, 57, and 58 have been cancelled by Applicant. New claims 65 and 66 have been added. Claims 40, 43, 44, 48, 56, and 59-66 are pending and under examination.

Response to Arguments

Objections/Rejections Maintained

Claim Rejections - 35 USC § 112, First Paragraph

Written Description - New Matter

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 40 and 48 are rejected and new claims 65 and 66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant argues that pore sizes of 200-700µm and 250-780µm are taught in the specification and that the claimed pore size range does not constitute new matter because each of the end limits of the range of 200-780µm have been disclosed in the application as originally filed (Remarks, pp. 11-12).

Applicant's argument has been fully considered, but it is not persuasive.

Applicant conflates the teachings in the specification for pore sizes and channel width, which are taught as separate and distinct ranges. As plainly explained of record, a range of 200-700µm for honeycomb pore sizes is taught in the specification at p. 40. A range of 250-780µm for channel width is taught in the specification at p. 36 (Table 1). However, a pore size range of 200-780µm is not taught in the specification. Applicant may not conflate different upper and lower range limits where the instantly claimed range is not specifically taught in the specification. Accordingly the amendments to claims 40 and 48 reciting a pore size range of 200-780µm constitutes new matter. See MPEP 2163.05 and *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), where the ranges described in the original specification included a range of "25%- 60%" and specific examples of "36%" and "50%." A

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corresponding new claim limitation to “at least 35%” did not meet the description requirement because the phrase “at least” had no upper limit and caused the claim to read literally on embodiments outside the “25% to 60%” range, however a limitation to “between 35% and 60%” did meet the description requirement.

New claims 65 and 66 are rejected for the reasons of record. Claims 65 and 66 are identical to claims 40 and 48 except that the new claims recite the apparatus "consisting of" instead of the “comprising” of claims 40 and 48. A pore size range of 200-780 μ m is also recited in new claims 65 and 66 and this pore size represents new matter, as set forth of record and herein.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 40, 43, 59, and 60 remain rejected and new claims 65 and 66 are rejected under 35 U.S.C. 102(a) as being anticipated by Hutmacher et al., (“Design and Fabrication of a 3D Scaffold for Tissue Engineering Bone”, as published in Agrawal et al., Eds *Synthetic Bioadsorbable Polymers for Implants*. ASTM, West Conchohocken, PA; May 2000, pp. 152-167).

Applicant argues the “objection under 35 USC 102” stating that Hutmacher should not be considered as prior art against the present application because three of the authors in Hutmacher are named inventors in the instant application, the effective filing date of the instant application is 20 September 2000, which is within one year from the date of publication of Hutmacher. Applicant’s argument has been fully considered, but it is not persuasive.

First, the instant rejection is a rejection, not an objection. Second, the cited prior art meets the limitation of a prior art reference under 35 USC 102(a). The prior art paper was published before the effective filing date in the instant case. Because the differences in the date are within a year, the rejection was made under 35 USC 102(a). Had the differences been more than one year, the rejection would have been made under 35 USC 102(b). Hutmacher remains an anticipatory reference for the reasons of record and the reasons set forth herein. Applicant is strongly advised to review MPEP 2132 and MPEP 715 for guidance on rejections under 35 USC 102(a).

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New claims 65 and 66 are also rejected for the reasons of record. Claims 65 and 66 are identical to claims 40 and 48 except that the new claims recite the apparatus "consisting of" instead of the "comprising" of claims 40 and 48. The cited references of record teach the limitations of claims 65 and 66 for the reasons stated of record and herein.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 40, 43, 44, 48, 50, 51, and 56-64 remain rejected and new claims 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richter et al., US Patent 6,280,478 (28 August 2001), benefit to 4 January 1999), Cima et al., US Patent 5,518,680 (21 May 1996, benefit to 23 February 1994),

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and Jang et al., US Patent 6,129,872 (10 October 2000, benefit to 29 August 1998), as evidenced by Kuslich, US Patent 5,549,679 (27 August 1996), for the reasons of record and the reasons set forth herein.

Applicant argues that in the “objection under 35 USC 103,” the Jang reference is nonanalogous art (Remarks, p. 9). Applicant argues that it is not understood how Kuslich evidences the combination of Richter, Cima, and Jang (Remarks, p. 9). Applicant argues that the recited lay-down pattern, in terms of angle degrees, is a species or subgenus and according to MPEP 2144.08(II) the claimed species/subgenus is not, by itself, obvious (Remarks, p. 10). Applicant argues that had the claimed lay-down pattern been predictable to a person of ordinary skill in the art, they would have been disclosed before the present invention (Remarks, pp. 10-11).

Applicant’s arguments have been fully considered, but they are not persuasive. As a preliminary matter, the instant rejection is a rejection, not an objection.

Applicant’s argument that the Jang reference is nonanalogous art is inaccurate and spurious. The claims are drawn to an apparatus that is formed of polymers and melt extrusion materials. Jang teaches an apparatus for creating three dimensional objects using solid free form fabrication (SFF) or layer manufacturing (column 1, lines 17-20) using X, Y, Z, planes (column 4, lines 21-23) using ceramics (column 11, lines 19 and 59), or polymers (column 11, lines 38-42, and column 12, lines 18-19). Jang teaches that the most popular file format used by all commercial rapid prototyping machines is the .STL format. The .STL format describes a CAD model's surface topology as a single surface represented by triangular facets. By slicing through the CAD model simulated by these triangles, one would obtain coordinate points that define the boundaries of each cross section (column 16, lines 44-50) (compare instant claims 40, 48, 57, 58, and 62). The ability to form “substantially equal porosities” is taught by the ‘872 patent at column 17, lines 6-27, which explains in detail how to delineate a boundary of a cross section and interior space may be controlled and automated, using a computer system wherein the programmed signals provide coordinates for polymer printing in a X, Y, and Z, axis, permitting the user to control the formation of the object of interest (compare instant claims 59 and 62). Jang is analogous art and teaches how one of skill in the art can arrive at the materially relevant limitations of the instant claims.

Regarding Applicant’s argument that Kuslich evidences the combination of Richter, Cima, and Jang, it is plainly stated of record in the Office Action mailed 7/10/2008 that the ‘679 patent provides evidence that the bioceramic hydroxyapatite (such as taught by the ‘478 patent and the ‘680 patent) is bioresorbable (see column 7, lines 49-50).

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Regarding Applicant's argues that the recited lay-down pattern, in terms of angle degrees, is a species or subgenus and according to MPEP 2144.08(II) the claimed species/subgenus is not, by itself, obvious, Applicant's argument is not well taken. The lay-down pattern is not a species or subgenus. It is related to the shape of the channels and pores in the claimed apparatus. Channels and pores of scaffold structure devices are old and well known. Further, the art of record teaches that changes in the shape of channels and pores in scaffold structure devices are readily made and many combinations are available using the software associated with FDM construction machines. The lay-down degree patterns claimed by Applicant are triangular and five-pronged in shape. As explained of record, argument as to the uniqueness of the triangular and five-sided pore shape, the '478 patent specifically teaches that the pore or channels sizes, mechanical strength of the lattice structure, and the directional properties of the lattice structure, can readily be modified or optimized for particular applications (column 5, lines 44-47). Additionally, the '680 patent teaches that it would be desirable to control pore size, shape and tortuosity, including connectedness, during the shaping operation (column 1, line 65 to column 2, line 2). The '478, '680, and '872 patents clearly teach that the lay-down pattern and the shape of the channels and pores can be varied, depending on the design and structural needs of the maker. As stated of record, the '478 patent teaches a customized three-dimensional, layered, scaffold structure for use in tissue engineering for an individual patient including the aspect of intercrossing filaments stacked in horizontal planes (see abstract; Figures 1 and 2; Examples 1 and 2, columns 3 and 4). Interconnected pores or channels are taught at column 1, line 27. Linear components and curved components are taught in Figure 1 and column 3, lines 1-34, especially lines 33-34. Components that can extend at any angle between 10 degrees and 90 degrees relative to those of an adjacent component are taught at column 3, lines 21-23 (see also column 4, lines 50-54). Thus, the variations in pattern lay-down, including variations in shape from round, to triangular, or five-sided, are known variations of the prior art and they would have been predictable to one of skill in the art at the time the invention was made. The motivation to choose particular angles comes from the '478 patent, which teaches that components can extend at any angle between 10 degrees and 90 degrees relative to those of an adjacent component are taught at column 3, lines 21-23 (see also column 4, lines 50-54).

Regarding Applicant's argument that had the claimed lay-down pattern been predictable to a person of ordinary skill in the art, they would have been disclosed before the present invention, Applicant's argument is spurious. As previously stated of record, design incentives to vary the pattern include variance in the purpose or anatomical placement of the scaffold (for example, differences in mechanical load strength and suture pull-out strength of the scaffold would vary depending on whether

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the scaffold was placed in or near a weight bearing anatomical part or subjected to intense mechanical stresses), improvements in offset yield strength, or improvements in porosity that could affect blood flow or cellular influx into the scaffold. Market forces would have also prompted the need for variations due to the lack of availability of scaffolds for an increasing variety of anatomical structures and competition in the market for product designed to meet specific anatomical and mechanical repair needs. These design incentives and market forces are also evidenced by the '478 patent, the '680 patent, and the '872 patent (see i.e. the '680 patent, column 1, lines 20-28). The composition (i.e. PLC and PLC/HA) of the claimed scaffold is old and well-known in the art, as demonstrated by the '680 patent. The only difference between the instant invention and the prior art is the lay-down pattern (i.e. shape) of the melt extrusion filament used to construct the scaffold apparatus. However, the '478, '680, and '872 patents clearly teach that this pattern can be varied, depending on the design and structural needs of the maker.

The variations in pattern lay-down are known variations of the prior art and they would have been readily predictable to one of skill in the art at the time the invention was made. See also, *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (holding that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant).

New claims 65 and 66 are rejected for the reasons of record. Claims 65 and 66 are identical to claims 40 and 48 except that the new claims recite the apparatus "consisting of" instead of the "comprising" of claims 40 and 48. The cited references of record teach the limitations of claims 65 and 66 for the reasons stated of record and herein.

Conclusion

NO CLAIM IS ALLOWED.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:30am-6:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647